DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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August 19, 2014

Aribex, Inc.
% Mr. Sanjay Ahuja
Director, Regulatory Affairs
744 South 400 East
OREM UT 84097

Re: K140723
Trade/Device Name: Nomad MD Handheld X-ray System
Regulation Number: 21 CFR 892.1720
Regulation Name: Mobile x-ray system
Regulatory Class: II
Product Code: IZL
Dated: June 5, 2014
Received: July 21, 2014

Dear Mr. Ahuja:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Janine M. Morris
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*
K140723

Device Name
NOMAD MD Handheld X-ray System

Indications for Use *(Describe)*
The NOMAD MD is a handheld and portable general purpose X-ray system. The device uses a fixed tube current and voltage (kVp) and, therefore, is limited to taking diagnostic X-rays of extremities.

It is intended to be used by a qualified and trained clinician on both adult and pediatric patients. It is not intended to replace a radiographic system with variable tube current and voltage (kVp) which may be required for full optimization of image quality and radiation exposure for different exam types.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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510(k) Summary

NOMAD MD Handheld X-ray System

Submitter:

Aribex, Inc.
744 South 400 East
Orem, UT 84097
Phone No: 801-226-5522
FAX No: 801-434-7233

Date of Summary:

March 14, 2014

Contact Person:

Christopher Dodge, Senior Regulatory Affairs Specialist or
Sanjay Ahuja, Ph.D., Director, Regulatory Affairs

Device Name:

- **Trade Name:** NOMAD MD Handheld X-ray System
- **Common Name:** Nomad MD
- **Classification Name:** Mobile X-ray system
- **Regulation:** 21CFR 892.1720
- **Product Code:** IZL

Predicate Device for Which Substantial Equivalence is Claimed:

MinXray HF 100H+ Portable X-ray Unit (K052721)

Device Description:

The NOMAD MD is a handheld, general purpose X-ray system that operates on 14.4 V DC supplied by a rechargeable NiCd battery pack. The X-ray tubehead, X-ray controls, and power source are assembled into a single hand-held enclosure. The package includes a spare battery, a Charging Cradle, and an AC-to-DC Power Supply.

Consideration was given to three FDA guidance documents, “Pediatric Information for X-ray Imaging Device Premarket Notifications” issued on May 10,

2012, “Radiation Safety Considerations for X-Ray Equipment for Hand-Held Use,” issued on December 24, 2008, and “Guidance for the Submission of 510(k)’s for Solid State X-ray Imaging Devices,” dated August 6,1999. Aribex determined that the solid state guidance did not apply to the NOMAD MD because it is an X-ray emitter and the guidance document is written for X-ray image recording systems, not for X-ray emitters.

Indications for Use/Intended Use:

The NOMAD MD is a handheld and portable general purpose X-ray system. The device uses a fixed tube current and voltage (kVp) and, therefore, is limited to taking diagnostic X-rays of extremities.

It is intended to be used by a qualified and trained clinician on both adult and pediatric patients. It is not intended to replace a radiographic system with variable tube current and voltage (kVp) which may be required for full optimization of image quality and radiation exposure for different exam types.

Summary of Technological Characteristics:

The NOMAD MD has been demonstrated to be substantially equivalent to the predicate device, the MinXray HF 100H+ Portable X-ray Unit (cleared under K052721). The proposed device has been verified and validated to satisfy the requirements derived from the indications for use and the substantial equivalence table.

NOMAD MD shares many of the same components and features as the predicate device including:

- Portable X-ray source
- Collimation of X-ray
- Two stage triggering mechanism
- Source to skin guard to limit distance between X-ray source and patient
- Constant potential waveform
- Similar user interface with tactile membrane pad with up-down push buttons for making selections
- Similar alerts and alarms that indicate equipment state of readiness to use

The MinXray operator instructions require that the operator “stand as far as possible from the X-ray unit while holding the exposure switch and pressing the button” in order to avoid being exposed to excess leakage and backscatter radiation.

The following is a comparison between Nomad MD (proposed) and the predicate device, the MinXray HF 100H+ Portable X-ray Unit (cleared under K052721).

Feature	MinXray HF100H+ (K052721)	Nomad MD X-ray System (K140723)
Regulation No.	21 CFR 892.1720	21 CFR 892.1720
Regulation Class	II	II
Product Code	IZL	IZL
Indications for Use/Intended Use:	Intended for use by a qualified/trained physician or technician on both adult and pediatric subjects for taking diagnostic x-rays.	The NOMAD MD is a handheld and portable general purpose X-ray system. The device uses a fixed tube current and voltage (kVp) and, therefore, is limited to taking diagnostic X-rays of extremities. It is intended to be used by a qualified and trained clinician on both adult and pediatric patients. It is not intended to replace a radiographic system with variable tube current and voltage (kVp) which may be required for full optimization of image quality and radiation exposure for different exam types.
Principle of Operation	General Purpose Diagnostic X-Ray	General Purpose Diagnostic X-Ray
TECHNOLOGICAL:		
Size: Body	8.75"Hx9.5"Wx15.35"L excluding skin guards	9.5”H x 5.25”Wx10”L (excluding Source Skin guard)
Weight	40.9 lbs.	11.0 lbs.
Source to skin distance	30 cm	30 cm
Focal Spot	1.2 mm	0.4 mm
Collimator	Four manually and steplessly adjustable shutters with light beam type central x-ray indicator (Advantech R72)	Four manually and steplessly adjustable shutters with LED Light Field Center Indicator
Triggering Mechanism	Two stage triggering	Two stage triggering
User Interface	Up-down push buttons for kVp selections and exposure time selections with LED indicators and mAs indicators.	Up-down buttons for exposure time selection, with timer display.
Energy Source	100-140 VAC 50/60 Hz	Rechargeable 14.4 V DC NiCd battery pack
Exposure Time	0.03-0.2 sec (in 0.01 sec Steps) 0.2-0.4 sec (in 0.02 sec Steps) 0.4-1.0 sec (in 0.05 sec Steps)	0.02 – 0.99 seconds in 0.01 increments

Feature	MinXray HF100H+ (K052721)	Nomad MD X-ray System (K140723)
	1.0-4.0 sec (in 0.1 sec Steps)	
mA	30 mA @ 40-60 kV 25 mA @ 62-80 kV 20 mA @ 82-100 kV	2.0 mA fixed
kVp	40-100kVp	75 kVp fixed
Waveform	Constant Potential	Constant Potential
Alerts and Alarms	As least two specific alerts and alarms indicate equipment state of readiness to use	Seven specific alerts and alarms indicating equipment's state of readiness to use
Class II Laser	Not a feature on this unit	Used to indicate the distance from the x-ray source to the target to be diagnosed.
User Interface Ease	Tactile membrane pad with audible signals indicates settings. Large illuminated digital exposure setting screen.	Tactile membrane pad with audible signals indicates settings. Large illuminated digital exposure setting screen.
Safety	Exposure switch button illuminates if unit misfires. The unit will lock up and needs to be restarted from the off position During the exposure an audible signal and the X-ray indicator illuminates.	Locked upon powering on with LC indicator, along with elongated audible signal. Unit will power down after 2.5 minutes of inactivity. After 10 seconds of being enabled, the unit will lock if exposure does not occur. Continuous audible signal is emitted along with indicator lights indicating that exposure is completed.
Low Battery Indicator and Audible Signal	Not a feature on this unit because it is AC/DC powered.	LED illuminates and flashes when battery charge is needs or needs recharging Audible signal indicates low battery signal
Electrical Safety Standards	UL 2601, IEC60601	IEC60601-1, EN60601-2
Performance Standard	21 CFR 1020.30	21 CFR 1020.30, 1020.31 IEC60601-3

Per the recommendations of the FDA Guidance document on "Radiation Safety Considerations for X-Ray Equipment Designed for Hand-Held Use," Aribex has incorporated internal shielding into the design of the NOMAD MD. This shielding, made from a proprietary bismuth blend, encapsulates the X-ray source assembly and prevents the operator of the device from being exposed to any appreciable amounts of leakage radiation. Test results indicate that the level of exposure is

well below the requirements of 21 CFR 1020.30(k). Evidence of the effectiveness of this internal shielding can be found in Section 19 NOMAD MD Performance Testing – Bench. Specifically, TP-0223, Test Case Scatter Radiation NOMAD MD, identifies the operator exposure dose within the significant zone of occupancy. See also QR-0200 Risk Analysis, NOMAD MD - Risk ID R009, R017.

Since the NOMAD MD, unlike its dental predecessor, is held on average 28 inches from the patient, it was not considered practical to incorporate an external backscatter shield into the design of the device. The effective size of the backscatter shield would need to be about three feet in diameter. For this reason, Aribex recommends in its operator manual (MP-0221, Section 3.3, Section 4.7[6], and Section 7.5) the use of a lead apron and thyroid collar when operating the NOMAD MD. Also see QR-0200 Risk Analysis, NOMAD MD - Risk ID R061.

As evidenced through Design Verification and Validation, NOMAD MD can produce diagnostic images of adult and pediatric extremities and they are of equivalent diagnostic quality as the MinXray device.

An extremity is generally defined as the distal or terminal portion of any bodily limb, or any portion of bodily limbs such as arms and legs. The NOMAD MD has been validated (see Section 19, TP-0302, Extremity Thickness Performance, NOMAD MD) to capture diagnostic quality images of body part extremities, such as fingers (from 1.5cm) and thighs (up to 21cm).

Based upon an analysis of the technological differences, and the substantiation through design verification and validation, Aribex determines that the safety and effectiveness of the proposed NOMAD MD is substantially equivalent to the MinXray predicate device and does not raise any new concerns.

Non-Clinical Test Data:

Performance bench testing was conducted as part of design control to ensure the safety and effectiveness of the NOMAD MD is equivalent to the predicate device. The safety and effectiveness of NOMAD MD for the proposed indications for use is substantiated through verification and validation testing on diagnostic images.

An image comparison study was also conducted by taking radiographic images of foot, knee, elbow, and hand phantoms using both the NOMAD MD and the predicate device. The images were then reviewed by a board-certified radiologist who determined that images from both devices were of diagnostic quality and, therefore, substantially equivalent.

Software documentation has been provided in Section 17 according to the FDA’s requirement for software that meets the moderate level of concern.

EMC and Electrical Safety testing on the NOMAD MD was performed and found to meet all the requirements in standards IEC 60601-1: 2005, IEC 60601-1-3:2008, IEC 60601-1-6:2010, IEC 60601-2-28:2010, IEC 60601-2-54:2009, IEC 60825:2007, IEC 62366:2007, and IEC 60601-1-2:2007.

Clinical Test Data:

Clinical testing was deemed not required to support the indications for use and therefore, it has not been conducted on the Nomad MD proposed product.

Conclusion:

Based on the comparison of the indications for use/intended use, the technological characteristics, and the operation of the device, Aribex concludes that NOMAD MD is substantially equivalent to the predicate device. In addition, based upon the review of the performance, standards analysis, and labeling, the differences between NOMAD MD device and the MinXray predicate device do not raise new concerns on safety and effectiveness for the proposed indications of use.